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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,122	10/13/2000	Alessandra Boe	P/717-181(CONT)	6984

1444 7590 12/02/2003

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,122	BOE ET AL.	
	Examin r	Art Unit	
	Joseph F Murphy	1646	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) *22-24 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 25-29* is/are rejected.

7)☒ Claim(s) *30 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Formal Matters

New claims 30-32 were added in the Paper submitted 9/5/2003. Claims 21-32 are pending. Claims 22-24 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). New claim 32 is withdrawn from consideration since it is drawn to a non-elected invention. New claim 32 is drawn to a method for treating autoimmune and inflammatory diseases by administration of TBP-2 and DHEA. This differs from the elected Group directed to a method for treating autoimmune and inflammatory diseases by administration of TBP-1 and DHEA because the methods are practiced with materially different starting materials, have materially different process steps, and a search of art on one Group would not reveal art on the other Group, thus imposing a burden to search on the Examiner.

Response to Amendment and Arguments

Applicant's arguments filed 9/5/2003 have been fully considered but they are not persuasive, for the reasons set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 25-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating septic shock by administration of a TNF receptor, or TBP-1 in combination with DHEA, does not reasonably provide enablement for a method of treating autoimmune and inflammatory diseases by administration of a TNF

receptor, or TBP-1 in combination with DHEA, for reasons of record set forth in Paper No. 13, 5/5/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection of record set forth that claim 21 is directed to a method of treatment of autoimmune and inflammatory disease in a patient by administration of DHEA in combination with a TNF receptor, while claims 25-29 are directed to methods of treatment of autoimmune and inflammatory diseases in a patient by administration of DHEA in combination with TBP-1. Thus, the claim encompass the treatment of any and all inflammatory and autoimmune diseases by administration of a TNF receptor, including TBP-1, in combination with DHEA.

Applicant argues that it was known in the prior art that TNF receptors are effective in treating autoimmune and inflammatory diseases of a broad scope, and that since the use of TBP-1 alone is known for treating a broad range of autoimmune and inflammatory diseases, the addition of the DHEA to the composition would not prevent the effect of the TBP-1 alone. Applicant cites several abstracts wherein the use of TNF receptors is shown to be effective in treating conditions such as RA, diabetes in NOD mice, and SLE. However, as set forth in the previous Office Action, the claims encompass the use of TNF receptor and DHEA to treat any and all autoimmune and inflammatory diseases. While the Specification demonstrates the effectiveness of the claimed treatment in a septic shock model, and the art teaches the effectiveness of TNF receptor alone in RA, SLE and the NOD mouse model of diabetes, this is not demonstrative of any and all autoimmune and inflammatory conditions, and does not enable one of skill in the art to treat any and all autoimmune and inflammatory conditions using the

claimed method. The previous Office Action cited art that teaches that TNF is not involved in all autoimmune and inflammatory disorders. The cited art recognizes that there are distinct disease processes involved in septic shock, other types of inflammation, and autoimmune diseases. Ulevich et al. teaches that the mechanism of septic shock is the binding of LPS by LPS Binding Protein (LBP) and the binding of LPS-LBP complex by CD14 (Ulevitch et al. at 438). The mechanism underlying the development of autoimmune and autoimmune inflammatory diseases is set forth in The Merck Manual which teaches that autoimmune disorders are the result of the immune system producing autoantibodies to an endogenous antigen with consequent injury to tissues. Mechanisms for the development of an immune response to autoantigens include, *inter alia*, the release of hidden or sequestered antigens into the circulation, the alteration of self-antigens into an immunogenic form, cross-reaction of a forging antigen with a self-antigen (Merck Manual, page 1061). In addition, the previous Office action also cited art showing that while the LPS model can be used to test the efficacy of therapeutic regimens for the treatment of septic shock, separate models are required to test the efficacy of the claimed treatments for efficacy in other inflammatory, or autoimmune diseases (U.S. patent No. 6,054,487, column 20, lines 20-35). No nexus is provided between the treatment of RA, SLE, the NOD mouse model of diabetes, or septic shock and any and all other inflammatory and autoimmune diseases. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass methods for which the skilled artisan would need to carry out experimentation to determine the effectiveness of the claimed treatment method in any and all other autoimmune and inflammatory conditions. Since the nexus between the treatment of RA, SLE, the NOD mouse model of diabetes or septic shock, and the treatment of any and all

autoimmune and inflammatory diseases is not set forth in the Specification, or recognized in the art, this experimentation would be undue since no teachings are provided that would allow one of skill in the art to predict that the claimed method would be efficacious in treating any and all other autoimmune and inflammatory diseases.

Conclusion

Claims 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21, 25-29 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
November 25, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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